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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,721	12/30/1999	MATTHEW S. REIMINK	1610.1US01	6766
22865	7590	01/06/2004	EXAMINER	
HON, SOW FUN				
ART UNIT			PAPER NUMBER	
1772				

DATE MAILED: 01/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/475,721

Applicant(s)

REIMINK ET AL.

Examiner

Sow-Fun Hon

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 November 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Dec. 01, 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ they raise the issue of new matter (see Note below);
(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment to advisory action.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 12012003.
10. ☒ Other: Attachment to advisory action

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Advisory Action

1. The request for reconsideration of claims 1-3, 5-20, 31-32 has been fully considered but does not place the application in condition for allowance for the reasons below.
2. Applicant argues that in the present application, the polymer itself, and not the substrate, provides the form of the device. Applicant is respectfully directed to the embodiment below:

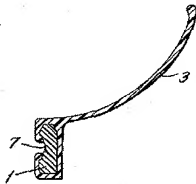


FIG. 3

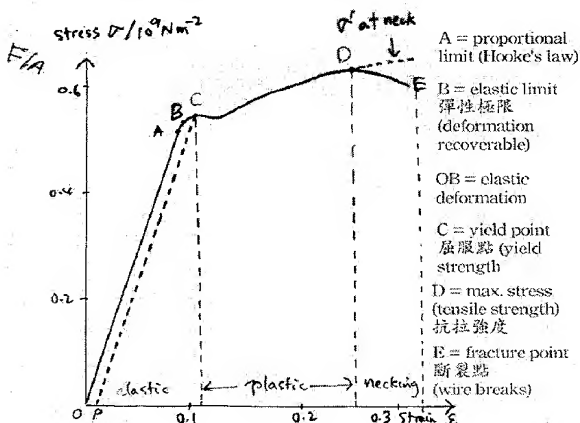
In Fig. 3, Pietsch et al. shows a cross-sectional view of the heart valve whereby the cusp material 3 encloses the support ring 1, and that the boundary edge of the cusp has a rounded lobar thickened outline (column 8, lines 20-30). It can be seen that the cusp 3 provides the form of the device. The cusp is made of flexible three-dimensionally crosslinked polymer (column 4, lines 20-30). The support ring is made out of inorganic material (stainless steel, ceramics) (column 10, lines 10-15). Thus it can be seen that the polymer (cusp) itself, and not the inorganic substrate, provides the form of the device.

3. Applicant argues that the cusps of Pietsch et al. are flexible, but are not made of a substrate and polymer composite. Applicant is directed to Fig. 3 above which shows that the cusp 2 extends all the way down, around and up over the support ring 1, which is a substrate and polymer composite.
4. Applicant argues that Pietsch et al. does not disclose a composite that can be bent at least about 100 degrees without extending the material beyond its elastic limit.

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Applicant is respectfully reminded that the evidence is present to indicate that the three-dimensionally crosslinked polydimethylsiloxane can be bent by at least 100 degrees while remaining elastic, and by about 180 degrees without extending beyond its elastic limit. The evidence is the teaching by Pietsch et al. that the three-dimensionally crosslinked polydimethylsiloxane has high fatigue strength in alternate bending, high breaking strength of at least 8 N/mm^2 at a low Shore A hardness of 25-35, and an elongation at break of more than 400 % (column 4, lines 60-65). The elastic limit of a material is defined below, wherein the deformation of the material is recoverable within the limit of the strain at the elastic limit. Pietsch et al. is stating that when a piece of the silicone rubber (crosslinked polydimethylsiloxane) is bent, or strained, it goes back to its original shape upon release of the bending force (strain) unless the force (or strain), is at least 8 N/mm^2 . Applicant has failed to demonstrate that the bending force, or strain, is at least 8 N/mm^2 .

Stress vs. strain graph for a ductile material



5. Applicant argues that Pietsch et al. does not teach that the support ring comprises a flexible composite of inorganic substrate and polymer, and that this composite can be bent, or to the degree noted in claim 10. Applicant is respectfully apprised that a support ring comprising a flexible composite of inorganic substrate and polymer is not presently claimed. Instead, a "medical device" is presently claimed which comprises a composite comprising an inorganic substrate and a polymer member covering at least a portion of the substrate. The term "comprising" means that the composite can form only part of the medical device. Furthermore, Fig. 3 below indicates that Pietsch et al. does indeed show a support ring 1 which comprises a flexible composite of inorganic substrate 1 and polymer cusp material 3.

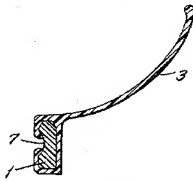


FIG.3

6. Applicant mentions Cromie as a reference being named as the primary reference in the 35 U.S.C. 103(a) rejection using MacGregor as the secondary reference. Applicant is respectfully apprised that Pietsch is correctly named as the primary reference. Applicant states that MacGregor's composite has the form of the article but does not specify in what way pertaining to the present claim language.

7. Applicant argues that there is no motivation to combine MacGregor with Pietsch et al. Applicant is respectfully apprised that MacGregor teaches that the composite has a fatigue endurance limit (107 cycles) of greater than 3000 psi shear strength anchor (column 5, lines 5-

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20), which provides the advantage and thus the motivation to have used the combination of rigid polymer, metal or ceramic and carbon of MacGregor in the invention of Peitsch et al. in order to obtain a heart valve with the desired fatigue endurance limit.

Applicant's arguments directed to the validity of Pietsch as the primary reference are addressed in the paragraphs above.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (703)308-3265. The examiner can normally be reached Monday to Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (703)308-4251. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9311.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.

SH
Sow-Fun Hon
12/15/03

[Signature]
HAROLD PYON
SUPERVISORY PATENT EXAMINER
1972 12/16/03

DETAILED ACTION

Rejections Withdrawn

1. The 35 U.S.C. 102(b) and 103(a) rejections in Paper # 14 (mailed 08/14/02) have been withdrawn due to Applicant's amendment in Paper # 19 (filed 04/25/03).

New Rejections

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1-8, 10-19, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Pietsch et al.

Pietsch et al. teaches a medical device comprising a composite having an inorganic substrate (support ring) and a polymer (plastic) covering at least a portion of the substrate, the polymer forming a structure substantially different from the structure of the substrate, and providing the form of the device (a heart valve whereby the support ring and the cusps are formed integrally as a result of the plastic skin, from which the cusps are formed, also enclosing the support ring, thus providing the form or shape of the device). The substrate (support ring) is made out of metal (stainless steel, titanium) or ceramics (column 3, lines 30-55). The polymer is crosslinked polydimethylsiloxane (silicone rubber), having high fatigue strength in alternate bending as well as a high breaking strength at a low Shore A hardness (column 4, lines 55-68 and column 5, lines 1-15). Crosslinked polyether-urethanes are also taught to be suitable with a low Shore A hardness and a high breaking strength (column 4, lines 20-55).

Since Pietsch et al. teaches that the crosslinked silicone rubber (polydimethylsiloxane) has high fatigue strength in alternate bending, a high breaking strength of at least 8 N/mm² at a low Shore A hardness of 25-35, and an elongation at break of more than 400 %, in the absence of a showing to the contrary, the examiner has taken the position that the composite can be bent by at least 100 degrees while remaining elastic, by about 180 degrees without extending the component beyond its elastic limit, and by about 60 degrees for about 40 million cycles to about 400 million cycles without significant structural failure.

Claim Rejections - 35 USC § 103

4. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pietsch et al. in view of Sumimoto Electric Co.

Pietsch et al. has been discussed above, and teaches the heart valve comprising a composite having an inorganic substrate and a polymer covering at least a portion of the substrate, the polymer forming a structure substantially different from the structure of the substrate, and providing the form of the device. Pietsch et al. fails to teach a diamond-like carbon coating over at least a portion of the silicone or urethane polymer.

Sumimoto Electric Co. teaches that coating by carbon or diamond of an artificial heart valve comprising polymer such as silicone polymer, polyurethane or PTFE gives the valve good antithrombosis property and good durability (abstract) thus providing the advantage and hence the motivation to coat the heart valve of Pietsch et al. with carbon or diamond in order to provide antithrombogenicity and improved durability.

Both Sumimoto Electric Co. and Pietsch et al. are directed to an artificial heart valve.

5. Claims 9, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pietsch et al. in view of MacGregor.

Pietsch et al. has been discussed above, and teaches the heart valve comprising a composite having an inorganic substrate and a polymer covering at least a portion of the substrate, the polymer forming a structure substantially different from the structure of the substrate, and providing the form of the device.

Pietsch et al. fails to teach that the polymer is rigid.

MacGregor teaches a heart valve made from a combination of rigid polymer(ic material), metal or ceramic and carbon. The metal substrate is given as an example (column 3, lines 20-30 and column 4, lines 30-50). The thickness of the rigid porous rigid plastic coating is taught to be about 20 to 300 microns and the composite has a fatigue endurance limit (107 cycles) of greater than 3000 psi shear strength. The polymer may be attached by flowing into the metal substrate thus forming a barb or anchor (column 5, lines 5-50).

Both Pietsch et al. and MacGregor are directed to an artificial heart valve.

Because MacGregor teaches that the composite has a fatigue endurance limit (107 cycles) of greater than 3000 psi shear strength, it would have been obvious to one of ordinary skill in the art to have used the combination of rigid polymer, metal or ceramic and carbon of MacGregor in the invention of Cromie in order to obtain a heart valve with the desired fatigue endurance limit.

Response to Arguments

6. Applicant's arguments with respect to claims 1-3, 5-20, 31-32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Sow-Fun Hon